A-1

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/782,435	02/18/2004	Pramod B. Mahajan	1121C	6412

27310 7590 08/25/2004

PIONEER HI-BRED INTERNATIONAL INC.
7100 N.W. 62ND AVENUE
P.O. BOX 1000
JOHNSTON, IA 50131

EXAMINER	
IBRAHIM, MEDINA AHMED	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/782,435	MAHAJAN, PRAMOD B.	
	Examiner	Art Unit	
	Medina A Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-27 are pending and are examined.

Specification

The disclosure is objected to because of the following informalities: for example, page 19, line 27, and page 69, line 18, contain an embedded hyperlink directed to an Internet address. The use of hyperlinks and/or other form of browser- executable code are not permitted under USPTO current policy because the content of such links are subject to a change, resulting in the introduction of New Matter into the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP 608.01.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 5 and 15-16 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The polynucleotide of claim 1 is from maize. A host cell comprising the polynucleotide of claim 1 reads a non-transformed maize cell that naturally contains the polynucleotide of claim 1 and cannot be patented. It is suggested that "comprising" in claims 5 and 15 be replaced with ---transformed with----.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, **first paragraph**, because the specification, while being enabling for the isolated nucleic acid sequence of SEQ ID NO: 3, a nucleic acid sequence encoding SEQ ID NO:4, recombinant expression cassette, transgenic plant/plant/seed comprising said sequence, and a method for transforming plants with said nucleic acid sequences, does not reasonably provide enablement for any isolated nucleic acid sequence having at least 80%, 85%, and 90% sequence identity to SEQ ID NO: 3 and encoding a polypeptide having RuvB activity or transgenic plant and plant cell or seeds comprising said nucleic acid sequence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicant broadly claims an isolated polynucleotide comprising a nucleic acid sequence having at least 80%, 85%, and 90% sequence identity with the disclosed sequence and encoding a polypeptide RuvB activity. However, Applicant has not provided sufficient guidance as how to obtain all nucleic acid sequences having said structural identity and still encoding a polypeptide with the desired functional activity. No specific guidance has been provided for any modification to SEQ ID NO: 3 that resulted in a nucleic acid sequence having both the structural and functional activity as recited in the claims. While the specification discloses other nucleic acid sequences from maize

identified as RuvB sequences, these sequences having not been shown to possess the recited structural properties.

While determination of sequence identity and assays of testing protein activity are well within the level of one skilled in the art, specific guidance are required to modify SEQ ID NO: 3 so that a nucleic acid sequences having both the desired structural and functional characteristics can be obtained. One skilled in the art would have to make all possible nucleotide substitutions and deletions in SEQ ID NO: 3, and test all nucleotide sequences that meet the structural limitation to determine which also meet the functional limitation. One would also have to evaluate the ability of the claimed variants to modulate the level of RuvB protein in plants.

The state of the prior art teaches that structural identity between two DNA/protein sequences does not inherently imply that the sequences have the same function, even if the % of sequence identity is relatively high. For example, Lazar et al (Molecular and Cellular Biology, March 1988, Vol. 8, No. 3, pp. 1247-1257 (U)) teach a mutation of aspartic acid 47 and leucine 48 of a transforming growth factor alpha results in different biological activities (see at least the Title). Applicants should note that the nucleic acid sequences encoding the proteins disclosed by either Lazar would share more than 80% sequence identity. Therefore, sequence identity alone cannot be used to predictably determine the function of a protein/DNA.

Therefore, given the lack of guidance as discussed supra, the unpredictability; lack of working examples, the state of the art, one skilled would not be able to practice

the invention as broadly claimed. See *In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)*

See *Amgen Inc. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021 and 1027 (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by its "physical or chemical properties" (e.g. a DNA sequence) and page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Written Description

Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant broadly claims an isolated polynucleotide comprising a nucleic acid sequence having at least 80%, 85%, and 90% sequence identity with the disclosed sequence and encoding a polypeptide RuvB activity. In contrast, the specification describes SEQ ID NO: 3 and three other maize nucleic acid sequences. These are genus claims.

The *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997) states "A description of a genus of cDNA may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. See also where the

court teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from the organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Applicant has not described the composition and structure of all nucleic acid sequences from any source having at least 80%, 85%, and 90% identity to SEQ ID NO: 3 and encoding a polypeptide having RuvB activity. Applicant has neither described a representative number of nucleic acid sequences encompassed by the genus of the claims nor provided a structural element common to all RuvB polynucleotide/polypeptide and that distinguishes the genus from all other DNA repair polynucleotides/polypeptides. Since Applicant has not described the nucleic acid sequences as broadly claimed, recombinant expression cassettes, host cells and plants comprising said nucleic acid sequences, and methods that employ said nucleic acid sequences are similarly not described. Therefore, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that one skilled in the art would recognize that Applicants are in possession of the invention as broadly claimed.

Therefore, weighing all factors above, the claimed invention does not meet the current written description requirements. See, also Written description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of U.S. Patent No. 6, 706, 949. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both the application and patent are directed to the nucleic acid sequence of SEQ ID NO: 3 or sequences having % identity thereof, a recombinant expression cassettes, host cells, and transgenic plant comprising said nucleic acid sequence, and a method for modulating the level of RuvB in a plant. The invention claimed in the application, drawn to a nucleic acid sequence having at least 80%, 85 or 90% sequence identity to SEQ ID NO:3, the recombinant expression cassette, host cell and transgenic plant comprising said nucleic acid sequence, and a method for modulating the level of RuvB in a plant are broader in scope than the nucleic acid sequence having at least 95% sequence identity to SEQ ID NO:3, the recombinant expression cassette, host cell and transgenic plant comprising said nucleic acid

sequence, and a method for modulating the level of RuvB in a plant claimed in the patent, and therefore fully encompasses the invention claimed in the issued patent. Therefore, the instantly claimed invention is obvious over the invention claimed in the issued patent.

Remarks

The claims are deemed free of the prior art because the prior art does not teach or reasonably suggest a nucleic acid sequence having at least 80%, 85%, or 90% sequenc identity to SEQ ID NO: 3. Nor that the prior art teaches, a recombinant expression cassette transgenic plant comprising said nucleic acid sequences, or a method that employs said nucleic acid sequence.

No claim is allowed.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

08/20/04

Mai

Medina A. Ibrahim

MEDINA A. IBRAHIM
PATENT EXAMINER